

REMARKS

The present application is a continuation-in-part of PCT/JP01/10234 filed November 22, 2001. Claims 1-19 were presented at the time of filing. In response to a Restriction Requirement dated November 1, 2005, Applicant elected the claims of Group I (claims 1-3 and 15-19); claim 15 was cancelled and rewritten as new claim 20. Claims 1-14 and 16-20 were, therefore, pending in the application with claims 4-14, 18 and 19 withdrawn from consideration as being directed to non-elected inventions. Claim 2 was cancelled in response to a non-final Office Action. Claims 16 and 20 are cancelled herein; claims 1, 3-14 and 17-19 remain pending in the application with claims 4-14, 18 and 19 withdrawn from consideration.

Claim Objection

Claims 1 is amended above in accordance with the Examiner's suggestion.

Rejection Under 35 U.S.C. § 101

Claim 16 is cancelled above rendering the rejection under 35 U.S.C. § 101 moot.

Rejection Under 35 U.S.C. § 112, first paragraph

Without acceding to the accuracy of the rejection, claims 16 and 20 are cancelled above rendering the written description and scope of enablement rejections of those claims under 35 U.S.C. § 112, first paragraph moot.

Rejection under 35 U.S.C. § 102

Claim 16 is cancelled above rendering the rejection of that claim under 35 U.S.C. § 102 moot.

Claims 1, 3 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ohnishi et al. (22<sup>nd</sup> Annual Meeting of the Molecular Biology Society of Japan) Program and Abstracts, December 7-10, 1999. According to the Office Action (as stated in the previous Office Action), Ohnishi et al. teaches the immunoprecipitation of a polypeptide referred to as "LICK" from a HeLa cell extract. The abstract discloses that the polypeptide is about 400 or 430 KDa, has kinase activity and has an internal sequence (approximately 25 amino acids in length) that is 100% identical to amino acids 2331 to 2356 of SEQ ID NO: 2 (3629 amino acids). The Office Action concludes that the instant claims are anticipated by the teaching of Ohnishi et al. and that a polypeptide obtained in accordance with the teachings of the abstract would inherently possess SMG-1 activity, thereby meeting that limitation of the present claims. Applicants respectfully disagree.

It is well settled that to serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). See *Bristol-Myers Squibb v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) ("To anticipate the reference must also enable one of skill in the art to make and use the claimed invention."). In the present case, neither the abstract nor the slide presentation by Dr. Ohnishi at the 22<sup>nd</sup> Annual Meeting disclosed the claimed polypeptide by structure or by a method of obtaining it. Additionally, one of skill, relying on the general knowledge in the art, would not have been apprised, based on the teachings of the abstract/presentation, how to obtain the claimed polypeptide. Thus, the reference not only fails to teach the claimed polypeptide, it is not enabled with respect to a method for obtaining the

claimed peptide and therefore, cannot anticipate the claimed invention.

As stated in the abstract, Ohnishi et al. “identified a human cDNA encoding a novel [member of the] PIKK family.” and “In immunoprecipitates derived from HeLa cells, we confirmed that both p400/430 exhibited an autophosphorylation activity...” The abstract further states that “Western blotting was carried out using plural specific antibodies *prepared in accordance with the sequence deduced from the cDNA...*”

The structure of the hSMG-1 cDNA, however, was not disclosed. Moreover, with the exception of a short stretch (25) of amino acids in the PIKK domain that are highly homologous to several other polypeptides, the sequence of the predicted translational product of the human SMG-1 cDNA was also not disclosed until the following year, at the 23<sup>rd</sup> Annual Meeting of the Molecular Biology Society of Japan. Thus, no structural information, either the nucleotide sequence of the cDNA or the amino acid sequence of the polypeptide was available from which one of skill in the art could generate an isolated hSMG-1 polypeptide and subsequently, raise an antibody specific for hSMG-1, so that the antibody could be used to isolate the claimed polypeptide by immunoprecipitation of a cell extract.

It is clear from the Detailed Description that cloning of the hSMG-1 cDNA and subsequent expression to obtain the gene product preceded and were necessary prerequisites for obtaining antibodies specific to that molecule, and that the information necessary for generation of a hSMG-1 polypeptide was not disclosed in the Ohnishi reference. Consequently, it would not have been a trivial matter to obtain antibodies specific to the claimed hSMG-1 polypeptide and without them, one of skill in the art would not have been able to simply immunoprecipitate the polypeptide from a cell abstract as suggested by the Office Action.

Thus, the disclosure in the abstract from the 22<sup>nd</sup> Annual Meeting abstract of various characteristics of the claimed polypeptide, does not teach or suggest either the claimed invention or a method for obtaining it. The Ohnishi reference, therefore, does not anticipate the claimed invention. Withdrawal of the rejection under 35 U.S.C. §102 in view of Ohnishi et al. is respectfully requested.

It is respectfully submitted that the above-identified application is now in a condition for allowance and favorable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,



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